LC 3416
2015 Regular Session
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D R A F T

SUMMARY

Permits pharmacist to substitute interchangeable biosimilar products for certain prescribed biological products. Directs State Board of Pharmacy to adopt rules to define "biological product," "biosimilar product" and "interchangeable" for purposes of prescription substitutions.

Becomes operative January 1, 2016.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to biological products; creating new provisions; amending ORS 689.508 and 689.515; repealing ORS 689.522 and section 5, chapter 342, Oregon Laws 2013; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.515 is amended to read:

689.515. (1) As used in this section unless the context requires otherwise:

(a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug **or biological product**, its container, label or wrapping at the time of packaging.

(b) "Dosage form" means the physical formulation or medium in which the **drug product or biological** product is intended, manufactured and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

(c) "Generic name" means the official title of a drug or drug ingredients

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

published in the latest edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

(d) "Substitute" means to dispense without the prescriber's express authorization a different drug product in place of the drug**, or an interchangeable biosimilar product in place of the biological product,** ordered or prescribed.

(e) "Therapeutically equivalent" means drugs that [*are approved by*] the United States Food and Drug Administration **has approved** for interstate distribution and [*the Food and Drug Administration*] has determined [*that the drugs*] will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

(2) Except as limited by subsections (3) and (5) of this section, unless the purchaser instructs otherwise, a pharmacist may substitute as follows:

(a) A drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent.

(b) A biosimilar product that is interchangeable with the prescribed biological product.

[*(b)*] **(c)** When the prescriber is not reasonably available for consultation and the prescribed drug **or biological product** does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug **or biological product** so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed **or will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen as the biological product prescribed**.

(3) A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug **or for the specified biological product** in a prescription.

(4) A pharmacy shall post a sign in a location easily seen by patrons at

the counter where prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute a less expensive drug **or biological product** [*which*] **that** is therapeutically equivalent to **or interchangeable with** the one prescribed by your doctor**,** unless you do not approve." The printing on the sign must be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

(5) A pharmacist may substitute a drug product **or interchangeable biosimilar product** under this section only when there will be a savings in or no increase in cost to the purchaser.

(6)**(a)** If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand [*which*] **that** is in stock.

(b) If the practitioner prescribes a biological product by a common name that indicates an interchangeable biosimilar product is available, the pharmacist shall, consistent with reasonable professional judgment, dispense or administer the lowest retail cost, effective interchangeable biosimilar product that is in stock.

(7) Except as provided in subsection (8) of this section, when a pharmacist dispenses a substituted drug **or interchangeable biosimilar product** as authorized by subsection (2) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug **or interchangeable biosimilar product**. If the dispensed drug **or interchangeable biosimilar product** does not have a brand name, the pharmacist shall label the prescription container with the generic name of the drug **or the common name of the interchangeable biosimilar product** dispensed along with the name of the drug **or interchangeable biosimilar product** manufacturer.

(8) A prescription dispensed by a pharmacist must bear upon the label the name of the medication in the container or shall be labeled as intended by

the prescriber.

(9) The substitution of any drug **or interchangeable biosimilar product** by a pharmacist or the pharmacist's employer pursuant to this section does not constitute the practice of medicine.

(10) A substitution of drugs **or interchangeable biosimilar products** made by a pharmacist or the pharmacist's employer in accordance with this section and any rules that the State Board of Pharmacy may adopt thereunder does not constitute evidence of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug **or interchangeable biosimilar product** was accepted in a generally recognized formulary or government list.

(11) Failure of a practitioner to specify that no substitution is authorized does not constitute evidence of negligence unless the practitioner knows that the health condition of the patient for whom the practitioner is prescribing warrants the use of the brand name drug product **or specifically prescribed biological product** and not the substituted drug **or interchangeable biosimilar product**.

(12) For purposes of this section, the board shall adopt by rule definitions for the terms "biological product," "biosimilar product" and "interchangeable." The rule defining the term "biological product" must be consistent with the provisions of 42 U.S.C. 262(i)(1). The rule defining "biosimilar product" must be consistent with the provisions of 42 U.S.C. 262 (i)(2) and (k)(3)(A)(i). The rule defining the term "interchangeable" must describe substituted biological products as meeting the standards in 42 U.S.C. 262(i)(3) and (k)(4) or standards determined by the United States Food and Drug Administration as set forth in the administration's latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 2. ORS 689.508 is amended to read:

689.508. The original record of every prescription filled by a pharmacy must be kept on file for three years at the pharmacy or as specified by State

Board of Pharmacy rule. The prescription record must contain the date of the transaction and the brand name, or if the drug **or biological product** has no brand name, the generic name and the name of the manufacturer of any drug**, or the common name and the name of the manufacturer of any interchangeable biosimilar product,** substituted pursuant to ORS 689.515. If the prescription may be communicated to the pharmacy by oral or electronic means, the prescription information may be recorded and stored in an electronic form that allows for ready retrieval. Prescriptions maintained [*in the file*] **as** required under this section must be readily accessible to the board for inspection.

SECTION 3. ORS 689.522 and section 5, chapter 342, Oregon Laws 2013, are repealed.

SECTION 4. (1) The amendments to ORS 689.508 and 689.515 by sections 1 and 2 of this 2015 Act become operative on January 1, 2016.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on or after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by the amendments to ORS 689.508 and 689.515 by sections 1 and 2 of this 2015 Act.

SECTION 5. This 2015 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2015 Act takes effect on its passage.